

TOWNSEND and TOWNSEND and CREW LLP

By: *Kenneth J. Paul*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Paul R. Hinton, et al.

Application No.: 10/822,300

Filed: April 9, 2004

For: ALTERATION OF FCN  
BINDING AFFINITIES OF SERUM  
HALF-LIVES OF ANTIBODIES BY  
MUTAGENESIS

Customer No. 20350

Confirmation No.: 1900

Examiner: Chun Crowder

Art Unit: 1644

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER  
37 CFR §1.97 and §1.98

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The documents cited on attached forms PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the documents AT, AU and BA-BH in compliance with the requirements of 37 CFR §1.98(a)(2) are enclosed. A copy of document AV was previously provided with copies of other documents and form PTO-1449 via an Information Disclosure Statement mailed October 28, 2004. Unfortunately, that earlier filed form PTO-1449 contained an error in the indicated publication date for document AV. The inclusion of the correct information in the current IDS is provided in the interest of compliance with 37 C.F.R. §1.98(b)(4).

The earlier filed form PTO-1449 also included a number of documents among AA to AM which were cited without compliance with 37 C.F.R. §1.98(b)(4). Therefore, Applicants have included them in the instant form PTO/SB/08A to provide compliance with 37 C.F.R. §1.98(b)(4).

It is respectfully requested that the cited documents be expressly considered during the prosecution of this application, and the documents be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and documents cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
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Reg. No. 44,461

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60929143 v1

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **1** of **2****Complete if Known**

Application Number	10/822,300
Filing Date	April 9, 2004
First Named Inventor	Hinton, Paul R.
Art Unit	1644
Examiner Name	Chun Crowder
Attorney Docket Number	011823-012611US

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-5,994,514	06/14/1991	Jardieu, et al.	
	AB	US-6,165,745	04/24/1992	Ward, et al.	
	AC	US-6,528,624	03/04/2003	Idusogie, et al.	
	AD	US-5,830,101	06/25/1996	Queen, et al.	
	AE	US-5,834,557	11/10/1998	Tao, et al.	
	AF	US-7,043,734 B2	08/01/2006	DelfAcqua, et al.	
	AG	US-6,797,493	09/28/2004	Sun, et al.	
	AH	US-20030044858A1	06/07/1992	Jardieu, et al.	
	AI	US-20030003098A1	04/05/1999	Siron	
	AJ	US-20020098193A1	03/03/1997	Ward	
	AK	US-20010033842A1	08/14/1991	Jardieu, et al.	
	AL	US-2006/0014934	01/20/2005	Hinton, et al.	
	AM	US-2003/0186840 A1	09/07/2006	DelfAcqua, et al.	
	AN				
	AO				
	AP				
	AQ				
	AR				
	AS				

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AT	PCT	WO04/092219	A2	10/28/2004	Protein Design Labs, Inc.		<input type="checkbox"/>
	AU	PCT	WO00/56361	A1	11/16/00	Zymogenetics, Inc.		<input type="checkbox"/>
	AV	PCT	WO02/60819	A2	08/08/2002	Modimmune, Inc.		<input type="checkbox"/>
	AW							<input type="checkbox"/>
	AX							<input type="checkbox"/>

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

50929143 v1

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/822,300
		Filing Date	April 9, 2004
		First Named Inventor	Hinton, Paul R.
		Art Unit	1844
		Examiner Name	Chun Crowder
		Attorney Docket Number	011823-012611US
Sheet	2	of	2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BA	ELLISON, Jay, et al. "Linkage and sequence homology of two human immunoglobulin $\gamma$ heavy chain constant region genes", <i>Proc. Natl. Acad. Sci. USA</i> (1982) 79:1984-1988	<input type="checkbox"/>
	BB	ATTWOOD, Terasa K. "The Babel of Bioinformatics", <i>Science</i> (2000) 290:1-5 (html format)	<input type="checkbox"/>
	BC	SKOLNICK, Jeffrey, et al. <i>Trends in Biotechnology</i> (2000) 18(1):34-39	<input type="checkbox"/>
	BD	REFF, Mitchell, E., et al. "A review of modifications to recombinant antibodies: attempt to increase efficacy in oncology applications", <i>Critical Reviews in Oncology/Hematology</i> (2001) 40:25-35	<input type="checkbox"/>
	BE	OGATA, Norio, et al. "Markedly prolonged incubation period of hepatitis B in a chimpanzee passively immunized with a human monoclonal antibody to the $\alpha$ determinant of hepatitis B surface antigen", <i>Proc. Natl. Acad. Sci. USA</i> (1993) 90:3014-3018	<input type="checkbox"/>
	BF	DATTA-MANNAN, A., et al. "Humanized IgG <sub>1</sub> Variants With Differential Binding Properties to the Neonatal Fc Receptor: Relationship to Pharmacokinetics in Mice and Primates", <i>Drug Metabolism and Disposition</i> , [published on Oct. 18, 2006 as doi:10.1124/dmd.106.011734 - DMD#11734, pages 1-47]	<input type="checkbox"/>
	BG	DATTA-MANNAN, A., et al. "Monoclonal Antibody Clearance: Impact of modulating the interaction of IgG with FcRn", <i>Journal of Biological Chemistry</i> [in press - published on November 29, 2006 as Ms. M607161200, pages 1-24]	<input type="checkbox"/>
	BH	DALL'ACQUA, William F., et al. "Properties of Human IgG1s Engineered for Enhanced Binding to the Neonatal Fc Receptor (FcRn)", <i>Journal of Biological Chemistry</i> (2006) 281(33):23514-23524	<input type="checkbox"/>
	BI		<input type="checkbox"/>
	BJ		<input type="checkbox"/>

Examiner Signature	Date Considered
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\* EXAMINER, initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language translation is attached.